

Comments

FDA’S DEFINITION OF DISEASE: FOREGONE OPPORTUNITY OR A PATH FORWARD IN IMPROVING REGULATION OF DIETARY SUPPLEMENTS?

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INTRODUCTION

Many suggest that the Food and Drug Administration (the ‘FDA’¹) does not adequately regulate dietary supplements.² Approximately one in five Americans reports using dietary supplements.³ Yet, as will be explained and documented later in this Comment, dietary supplements can be dangerous, cause a person to forgo proper healthcare, and be a waste of money. The FDA can regulate dietary supplements by monitoring the claims borne on labels. Roughly speaking, drugs and the claims that drugs carry on their labels are highly regulated, whereas dietary supplements and the claims they bear on their labels face less stringent standards. Consumers, unaware of the FDA’s regulatory structure, have a hard time distinguishing between drug claims and dietary supplement claims.⁴ The FDA has solicited studies on consumer interpretation of labels and found mixed results.⁵

1. FDA sometimes mentions the term ‘disease’ with single quotation marks, and sometimes with double quotation marks. This Comment uses single quotation marks to mention, but not use, a word or phrase, unless within the context of a quotation of the work of another, in which case the punctuation is left as it is in the original. To illustrate, ‘disease’ has seven letters (and is thus a mentioning of the term), but disease does not have seven letters (and is thus a use of the term). Moreover, this Comment uses double quotation marks either to quote a source, or to use as scare quotes, which indicate that a term is used in an abstracted sense. The phrase ‘the concept of’ refers to what people ordinarily think of something, independent of its technical, ostensive definition.

2. See, e.g., Alessa Thomas, Note, *Making Sense of Supplements: Suggestions for Improving the Regulation of Dietary Supplements in the United States*, 2010 MICH. ST. L. REV. 203 (2010) (arguing for Congressional action in changing regulation of dietary supplements); Jennifer Akre Hill, Note, *Creating Balance: Problems Within DSHEA and Suggestions of Reform*, 2 J. FOOD L. & POL’Y 361 (2006) (same); Iona N. Kaiser, Note, *Dietary Supplements: Can the Law Control the Hype?*, 37 HOUS. L. REV. 1249 (2000) (same).

3. Rob Stein, *Alternative Remedies Gaining Popularity*, WASH. POST, May 28, 2004, at A1 (containing a government survey of 31,000 people).

4. For example, one study found that consumers who trusted that the government would not allow useless or dangerous products to enter the marketplace and consumers who tended to discount disclaimers borne on dietary supplements both believed their biases were confirmed. Karen France & Paula Bone, *Policy Makers’ Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels*, 39 J. OF CONSUMER AFFAIRS 27, 34 (2005). See generally Matthew Lindsey, Note, *Dietary Supplements and Structure-Function Claims: The Dysfunctional Structure of Current Regulation*, 5 J. FOOD L. & POL’Y 201 (2009) (providing a general discussion of the problems with FDA regulation of dietary supplement claims).

5. *Transcript of Public Meeting: Assessing Consumer Perceptions of Health Claims, November 17, 2005*, FDA, available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm109638.htm> (last visited Apr. 13, 2013) (discussing how in some cases the results of FDA-solicited research are surprising. For example, claims that scientists had thought would be moderately trustworthy were interpreted by consumer

The following examples will help illustrate the difficulty that consumers (and the FDA) face in making informed, rational choices about their health. A dietary supplement website sells a product that advertises the following claim:

Alpha Lipoic Acid (ALA) is an antioxidant that has two main benefits. The first benefit is the removal of free radicals from your body and the functional enhancement of other antioxidants, such as vitamins A, C and E. Free radicals are waste products that are created when your body turns food into energy. Ridding your body of free radicals could deter the onset of many health related problems. The second benefit of ALA is its “insulin mimicking” effects - the dramatic decrease in glucose levels. Insulin mimicking also provides increased concentrations of glutathione in the cells, which has been shown to speed up recovery from weight training. It also enhances muscle cell nutrient intake and protein turnover.⁶

Alternatively, perhaps comically, another website sells a product that advertises the following claim:

Lucidrol is scientifically designed to push the minds' [sic] focus, cognitive clarity and cerebral sharpness to previously unachievable levels. In today's stressful environment, we all struggle with the constant demands from work, personal relationships and most importantly, our daily training regimen. Quality training demands the mind be focused in a way that maximizes the precious time spent in a gym environment. If you can achieve tunnel vision - a single enhanced focus on the goals ahead—you will achieve desired results—whatever they may be. Lucidrol—Ultra Cognitive Enhancer Achieve Tunnel Vision Stimulant Free.⁷

As will be explained in further detail later later, the first claim (for ALA) needs pre-market approval of a certain sort, while the second claim (for Lucidrol) does not, though the FDA requires all claims be truthful and not misleading. With claims such as the one accompanying Lucidrol, it is hard to get at the precise problem, because the claims use vague terminology.

subjects as being *more* trustworthy with a disclaimer—that a claim had *not* been reviewed by the FDA—than claims without such a disclaimer).

6. *Universal Nutrition Alpha Lipoic Acid 100mg, 60 Capsules*, A1SUPPLEMENTS, <http://www.a1supplements.com/Alpha-Lipoic-Acid-100mg-60-Capsules-p-17094.html> (last visited Apr. 13, 2013). A1Supplements is based in Louisville, Tennessee.

7. SUPPLEMENT WAREHOUSE, http://www.laurbanfitness.com/shop/product_view.asp?id=2144665&StoreID=5960A85CA8DB4D57959B40AC607865BF&private_product=1 (last visited Apr. 13, 2013). The Supplement Warehouse has its corporate headquarters in Milwaukee, Wisconsin.

Lucidrol does not bear a claim that it cures disease, yet does seem to claim that it can enhance the body's function beyond what is normal—a claim that one would think would require substantial scrutiny. The reader is encouraged to explore the websites mentioned for other examples of claims about dietary supplements. This is obviously dangerous. If the claims borne by dietary supplements are vague, and FDA regulation is lax, regulatory problems will ensue.

Looking at the issue of regulation of dietary supplements abstractly rather than how the FDA, in fact, regulates dietary supplements, there are a number of ways that the FDA could improve regulation of claims made on such products. The FDA could: (1) enhance its post-market review of claims relating to dietary supplements, (2) require pre-market approval for such claims, (3) greatly restrict the content of such claims by outright prohibition, as with a list, or (4) greatly expand the category of so-called “disease claims” so as to catch more of the inappropriate claims made about dietary supplements. This essay develops and defends the fourth proposal.

In 1998 and 1999, the FDA considered changing its definition of disease in accordance with the wishes of many health care practitioners and against the wishes of many in the dietary supplement industry. The FDA opted to forgo the opportunity. The thesis of this Comment is that the FDA could better regulate dietary supplements by first improving its definition of disease and second by removing all references to disease in its regulations altogether. A great deal of legal scholarship in this area focuses on changing or repealing the statute that sets up the regulatory framework for dietary supplement claims.⁸ This Comment has a different approach—it focuses on problems inherent in FDA's regulations and proposes change within FDA's claimed statutory authority about dietary supplement claims.

8. There are a few proposals in scholarship for the FDA to more stringently regulate other areas of the dietary supplement industry, such as manufacturing. See, e.g., Lars Noah & Barbara A. Noah, *A Drug By Any Other Name. . .?: Paradoxes in Dietary Supplement Risk Regulation*, 17 STAN. L. & POL'Y REV. 165 (2006) (proposing that the FDA assume control over dietary supplements on the basis of manufacturing processes and over safety in accordance with current statutory authority). This Comment focuses on FDA regulation of claims borne by dietary supplements.

I. THE FDA'S DEFINITIONS OF 'FOOD,' 'DRUGS,' AND 'DIETARY SUPPLEMENTS,' AND CORRESPONDING REGULATIONS

A. *FDA's Definition of 'Food' and Corresponding Regulation*

The Food Drug and Cosmetic Act of 1938 ('FD&C Act') gave the FDA authority to regulate, in varying ways, food, drugs, cosmetics and medical devices.⁹ The term 'food' has a technical meaning for the FDA in the FD&C Act: (1) articles used for food and drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.¹⁰

In the FDA's technical definition, the term 'food' is used ambiguously, both in its ordinary, colloquial sense embedded in the FDA's technical definition of 'food' and also in its technical sense to include gum, drink, ingredients, etc. Note that there is explicit reference to the "use" of a product, implying that the relevant criterion is what the product is used for, rather than the purpose for which it is made, distributed or sold. The colloquial use of 'food,' (1) has been interpreted as indicating an article used "primarily for taste, aroma, or nutritive value."¹¹ Throughout the remainder of this Comment, 'food' will refer to its technical FDA definition.

For the purposes of this Comment, the focus of the FDA's regulation of food will be in the context of labeling. Under the FD&C Act, food cannot be misbranded in the sense that the label cannot be "false or misleading in any particular."¹² The FD&C Act has numerous specific requirements, such as a requirement that the label contain a list of ingredients, in descending order of predominance.¹³ Also, food labels can contain nutrient claims of certain sorts.

Under the current regime, food can bear a so-called "health claim." The three types of health claims are: (1) implicit health claims (reference to the nutrient content of food), (2) general health claims (reference to promotion of health), and (3) explicit health claims (reference to the prevention of specific diseases).

Explicit claims are similar to disease claims that drugs can bear. Disease claims consist of two components: a substance and a related

9. Food, Drug & Cosmetic Act, 21 U.S.C. §§ 321–99 (1938) [hereafter FD&C Act].

10. *Id.* § 321(f). Some items colloquially referred to as "food" are not under the FDA's jurisdiction, such as meat, which falls under the jurisdiction of the USDA. Set aside this qualification for this Comment.

11. *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983).

12. FD&C Act § 403(a).

13. FD&C Act § 403(i).

condition.¹⁴ Disease claims assert that a substance diagnoses, treats, prevents, cures, or mitigates a specific disease or disease generally.¹⁵ For the purposes of this Comment, the third class of health claims will be called ‘disease-prevention claims’ and this class is not to be understood as so-called “disease-claims.” Understandably, this terminology is confusing, yet the FDA uses such terms in its regulations. All disease-prevention claims for food, small though the set may be, must be approved by the FDA prior to labeling.¹⁶ There are two categories of disease-prevention claims for foods: qualified disease-prevention claims and unqualified disease-prevention claims. A *qualified* disease-prevention claim for food is pre-approved only if there is credible scientific evidence that supports it.¹⁷ An *unqualified* disease-prevention claim for food is pre-approved only if there is significant scientific agreement about the claim.¹⁸ Although the standards for food disease-prevention claims are somewhat vague, FDA treats these as very restricted classes. There are only twelve unrestricted disease-prevention claims approved for food.¹⁹ Examples include a link between: (a) calcium and osteoporosis, (b) sodium and hypertension, and (c) fiber-containing grain products, fruits, and vegetables and cancer.²⁰

The relatively new, fourth category of health claims for foods was defined in the Nutrition Labeling and Education Act of 1990 (‘NLEA’) and subsequent notices. The fourth health claim provides “dietary guidance” to consumers.²¹ Such guidance does not make reference to either of the elements of a disease claim (the substance and the disease-related condition).²² Dietary guidance, unlike disease-prevention claims for food, does not require pre-approval, but rather, merely FDA notice. The FDA’s conception of this sort of health claim is somewhat inchoate, and the category is still being shaped by public and private input.²³

There is another important class of claims that foods can bear—structure-function claims. Structure-function claims are discussed in the context of dietary supplements in Part I.C., *infra*, and more substantially thereafter.

14. 58 Fed. Reg. 2,478, 2,487 (Jan. 6, 1993).

15. FD&C Act § 403(r)(6).

16. 68 Fed. Reg. 66,040, 66,041 (Nov. 25, 2003).

17. *Id.*

18. *Id.*

19. 21 C.F.R. § 101, subpart E.

20. *Id.*

21. 58 Fed. Reg. 2,478, 2,487 (Jan. 6, 1993).

22. *Id.*

23. See 68 Fed. Reg. 66,040 (Nov. 25, 2003) (explaining the FDA’s rationale behind the proposed rulemaking for dietary guidance health claims).

B. The Definition of 'Drug' and Corresponding Regulation

Under the FD&C Act, the term 'drug' has a specific technical meaning.

The term 'drug' means: (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B) or (C).²⁴

The FDA's definition of the term 'drug,' like the definition of 'food,' includes the concept of use rather than design. 'Drug' is defined in such a way that no drug can also be food. For purposes of jurisdiction, the definition of 'drug' is in a sense part of a disjunction within the regulatory framework of the FDA, since a product that does not meet the definition, but makes a "disease claim," is thereby subject to regulation as a drug.

The FDA asserts that it has jurisdiction over products as drugs by virtue of a product merely meeting condition (C) of its definition. The FDA's definition of drug, however, is not entirely disjunctive. For example, the United States Pharmacopoeia includes express dietary supplements, and courts have been hesitant to treat a product's meeting condition (A) as sufficient to establish drug-jurisdiction over that product.²⁵ Meeting condition (B) alone is also sufficient to establish drug jurisdiction. This will be explained in greater detail later in this Comment.

Drugs are subject to a much more stringent set of FDA regulations than foods. Prior to the FD&C Act (recall that the first statute is from 1938), drugs had only been regulated at the point of sale or use.²⁶ By requiring that the FDA receive notification of all new drugs ('pre-market notification'), the FD&C Act gave FDA power of review. Later, in 1962,

24. FD&C Act, 21 U.S.C. § 321(g)(1) (2006).

25. PETER BARTON HUTT, *FOOD AND DRUG LAW*, 40 (3d ed. 2007) (citing *National Nutritional Foods Assoc. v. FDA*, 504 F.2d 761, 788–89 (2d Cir. 1974) and *National Nutritional Foods Assoc. v. Mathews*, 557 F.2d 325, 337–38 (2d Cir. 1977)) (describing the courts' hesitancy to allow FDA drug jurisdiction over products listed in the works mentioned in (A)). Whether the section of the Pharmacopoeia (dealing with dietary supplements) is a supplement to the official United States Pharmacopoeia listing might not be material, as (A) includes supplements. See *USP Verification Services*, U.S. PHARMACOPEIAL CONVENTION, available at <http://www.usp.org/USPVerified/> (last visited Apr. 13, 2013).

26. Food and Drug Act of 1906, 21 U.S.C. §§ 1–15 (2006) (repealed 1938).

the FDA gained the power of review over whether a drug is safe, effective, and properly labeled ('pre-market approval'). The burden of proof is on the drug-maker, and the standards that the FDA employs are high. The FDA's regulation of drugs includes, but is not limited to, labeling. For example, access to drugs is based on a distinction in the FD&C Act between prescription and over-the-counter drugs.²⁷ Any drug that falls under the prescription regulations, yet is sold without a prescription, is thereby mislabeled.²⁸ The FDA's regulation of drugs is thus much more stringent than its regulation of foods.²⁹ Correspondingly, drugs labels can make much more significant claims, such as disease claims.

The class of disease claims includes statements of many kinds. The Code of Federal Regulations contains a list of disease claims.³⁰ For example, no claim can be made that a product "(i) has an effect on a specific disease or class of diseases [or] (ii) has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology."³¹ Also, a claim that a product "[h]as an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm" is forbidden.³² Other factors taken into account are the name of the product, statements about the formulation of the product, and citations to other sources.³³ Most importantly, though, any claim that a product is intended "to diagnose, mitigate, treat, cure, or prevent disease" is a disease claim.³⁴

C. FDA's Definition of 'Dietary Supplement' and Corresponding Regulation

Colloquially, dietary supplements might seem to be food or drugs, given FDA definitions thus far. Dietary supplements are used for both food and drink in an ordinary sense. However, it might seem that dietary supplements may be used in the diagnosis, cure, mitigation, treatment or prevention of disease, or that they are intended to affect the structure or

27. FD&C Act § 503(b)(1), 21 U.S.C. § 535(b)(1) (2006).

28. *Id.*

29. Admittedly, this Comment does not fully explore the FDA's regulations of food and drugs, but for the purposes of this Comment, this basic account is sufficient.

30. 21 C.F.R. § 101.93(g)(2).

31. *Id.*

32. *Id.*

33. 21 C.F.R. § 101.93(g)(2)(iv)(A)-(E).

34. *Id.*

functions of the body. Alternatively, dietary supplements might fall into a middle ground, somewhere between food and drugs.

Despite how dietary supplements seem to be categorized by the ordinary consumer, the FDA is clear that dietary supplements are classified as food. In the FD&C Act, Congress gave the FDA the power to regulate, to some extent, the labeling of “vitamin, mineral, and other dietary properties [of food,]” if it “is represented for special dietary uses.”³⁵ Dietary supplements more clearly fall under the definition of those foods represented for special dietary uses. However, the FD&C Act is far from Congress’ most recent word on dietary supplements. The FDA struggled for years to better regulate dietary supplements.³⁶ After a series of small regulatory changes regarding what the ordinary consumer would think of as dietary supplements, Congress enacted the Dietary Supplement Health and Education Act in 1994 (‘DSHEA’).³⁷ The DSHEA made an explicit classification for dietary supplements within the class of foods. Hutt describes the DSHEA as “an even more overwhelming and humiliating defeat for FDA than [earlier Congressional actions].”³⁸

The following is the DSHEA definition of “dietary supplement”:

The DSHEA defines “dietary supplement” as:

- (1) [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
- (2) [] a product that—
 - (A)(i) is intended for ingestion in a form described in section [411](c)(1)(B)(i) of this title; or (ii) complies with section [411](c)(1)(B)(ii) of this title;
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

35. FD&C Act § 403(j), 21 U.S.C. § 343(j) (2006).

36. Peter Barton Hutt, *U.S. Government Regulation of Food with Claims for Special Physiological Value*, in HUTT, *supra* note 25 at 261.

37. Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417, 108 Stat. 4325 (1994) (codified at 21 U.S.C. § 301 (2006)).

38. See HUTT, *supra* note 25 at 261.

(C) is labeled as a dietary supplement[.]³⁹

First, note that subsection (E) is a catch-all group, in that it includes any dietary substance for use to supplement the diet. This seems to have a broad scope and could include substances one might assume to be drugs. Second, with certain qualification, a dietary supplement must be intended for ingestion. Thus, dietary supplements, for the most part, must be taken by mouth and ingested.

Nothing in this definition explains Hutt's assertion that the DSHEA was an unusually overwhelming and humiliating defeat for FDA. These are just definitions, and seem natural definitions for a regulatory body to employ, given the subject matter. In order to explain Hutt's evaluation, one must proceed to the regulations that accompany the definitions.

Dietary supplements, by virtue of being classified as foods, are subject to the labeling requirements of foods, such as the requirements of the 1938 FD&C Act that dietary supplement labels cannot be false or misleading. The DSHEA in 1994, however, set up a special regulatory regime for dietary supplements, which permitted labels to make new kinds of claims for dietary supplements. These new label claims would have rendered the dietary supplements 'drugs' under the FD&C Act. Specifically, the DSHEA allows labels to contain statements that describe "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that characterize "the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."⁴⁰ Call these "structure-function claims."

Structure-function claims are not disease claims. Rather, they assert only that a dietary supplement stimulates, maintains, supports, regulates or

39. FD&C Act § 201(ff), 21 U.S.C. 321(ff)(2006). Section 411(c)(1)(B) refers to a food which "(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or (ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet." 21 U.S.C. 350(c)(1)(B) (2006).

40. FD&C Act § 403(r)(6), 21 U.S.C. § 343(r)(6)(A)(2006). Although the FDA's definition of disease does not play a prominent role in Hutt's seminal casebook, the definition is a regulation and plays a key role in numerous FDA guidance documents. See, e.g., *Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide*, U.S. FOOD AND DRUG ADMINISTRATION, (Jan. 9, 2002), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340.htm>. The guide is set up for small dietary supplement makers, marketers, and sellers who might not have easy access to an attorney. "Small" is defined as having "total annual revenues of less than \$20 million." *Id.* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,628 (proposed Apr. 29, 1998) (to be codified at 21 C.F.R. pt. 101). Therefore, it is likely that some "small" dietary supplement companies have easy access to attorneys, but not all such companies.

promotes proper function in the human body.⁴¹ The FDA defines disease in the following way:

For purposes of 21 U.S.C. § 343(r)(6), a 'disease' is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.⁴²

This definition of disease is specific to the section of the U.S. Code on dietary supplements. Thus, it does not have to be used by FDA in its regulation of products that make disease claims under the drug regulation scheme. Set this aside for now. The definition of disease within section 343(r)(6) provides two ways for a biological state to qualify as a disease claim.⁴³ First, the damage clause entails damage to a biological state or function; an improper function constitutes a disease. Alternatively, the causal clause entails that a state of health leading to such dysfunction also constitutes a disease. These clauses are disjunctive. Lastly, there is an exception to the 'disease' definition for regulatory purposes: The exception for essential nutrient deficiencies permits certain foods to make disease claims only if and because those foods would cure the nutrient deficiency disease.⁴⁴

Dietary supplements may contain structure-function claims but not disease claims.⁴⁵ Such structure-function claims may contain an assertion that some products stimulate, maintain, support, regulate or promote structure or function.⁴⁶ Labels that include a structure-function claim must also claim the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."⁴⁷

41. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 21 C.F.R. § 101.93 (2012).

42. Certain Types of Statements for Dietary Supplements, 21 C.F.R. § 101.93(g)(2012).

43. 'Disease' will be understood in the FDA's sense for the remainder of Part I of this Comment.

44. There are further regulations on the essential nutrient deficiencies exception, such as requirement of a statement of the prevalence of the nutrient deficiency disease in the general population.

45. Dietary supplements, being foods, can make disease-prevention claims in certain circumstances, but these are health claims, not disease claims.

46. FDA COMMISSION ON DIETARY SUPPLEMENT LABELS, GUIDANCE AND RECOMMENDATIONS, *reprinted in* HUTT, *supra* note 25, at 280.

47. In the example of Lucidrol, a disclaimer appears at the bottom of the Lucidrol advertisement. The statement is not hidden, though one has to scroll down to see it past the product description and the "buy it" link. The disclaimer for ALA is visible without

As noted above, Hutt claims that the DSHEA was a “humiliating defeat” for FDA. This is so because the FDA wanted to regulate structure-function claims. Prior to the DSHEA, FDA largely treated structure-function claims as drug claims. FDA’s only real concession in the DSHEA was the disclaimer that must accompany any structure-function claim. However, this is a small concession given that FDA sought to stringently regulate structure-function claims.

D. Public Policy and FDA Regulation of Dietary Supplements

The FDA is concerned primarily with public health and claims that without their regulations the public at large would be in danger.⁴⁸ The FDA also has other concerns, such as reducing fraud and other undesirable market practices, but these are comparably weak priorities compared to the goal of protecting and promoting public health.⁴⁹

With regard to dietary supplements in particular, the FDA has a more complex line of concerns. In the arena of dietary supplements, the FDA has five competing values: (1) public health,⁵⁰ (2) waste of money and fraud, (3) freedom of consumers, (4) commercial free speech,⁵¹ and (5) foregone healthcare. A number of books and articles focus on the public health issue and argue that the DSHEA is somehow inadequate.⁵² FDA

scrolling down. The reader is encouraged to go to the websites in the introduction and examine the contexts of the disclaimer.

48. See *What We Do*, FDA, available at <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last updated June 19, 2012) (asserting in its mission statement that FDA is responsible for protecting public health).

49. *Id.*

50. *Id.*

51. Gerald F. Masoudi, *Developments in Food and Drug Law*, 60 FOOD DRUG L.J. 107 (2005); Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31 (2011).

52. See, e.g., DAN HURLEY, *NATURAL CAUSES: DEATH, LIES, AND POLITICS IN AMERICA’S VITAMIN AND HERBAL SUPPLEMENT INDUSTRY* (2006) (detailing the dangers of the dietary supplement industry); Lauren Manning, *The Skinny on the Fop Flop: Why the FDA Must Tighten the Belt on Fop Labeling in Light of the Obesity Crisis*, 38 HOFSTRA L. REV. 1227 (2010) (arguing that FDA regulation of weight-loss claims on dietary supplements is inadequate in light of the obesity crisis); Rahi Azizi, Comment, “Supplementing” the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplemental Health and Education Act, 98 CALIF. L. REV. 439 (2010) (arguing that FDA fails to regulate “nutraceuticals”—functional foods taken to enhance health, such as botanical products—adequately); Joseph K. Dier, Comment, *S.O.S. from the FDA: A Cry for Help in the World of Unregulated Dietary Supplements*, 74 ALB. L. REV. 385 (2010-2011) (arguing for a repeal of DSHEA on public health grounds); Richard Nowak, Comment, *DSHEA’s Failure: Why a*

clearly treats some values as more important than others. For example, it does not heavily regulate products that bear anti-aging claims.⁵³ Perhaps the FDA is less concerned about foregone healthcare with products that bear anti-aging claims, since aging is a universal, unpreventable process.

II. FURTHER DISCUSSION OF FDA'S DEFINITION OF 'DISEASE'

Although it has not been discussed in the literature, the FDA's definition of disease bears little resemblance to the ordinary concept of disease. This Comment will discuss how the FDA's definition is both overbroad and underbroad in comparison with the ordinary concept of disease. Moreover, it will show that the boundary between structure-function claims and disease claims is not clear. All of this leads to confusion about the regulation of dietary supplements.

I will begin with the matter of overbreadth of the FDA's definition. Imagine that a dietary supplement manufacturer sells a product called "Skele-grow." The label of Skele-grow bears the claim: "Skele-grow aids the bone-growth process in case of broken bones." This is a disease claim—the sort of claim that the FDA must regulate heavily. Yet broken bones are not, according to the ordinary concept, diseases. Indeed, the FDA would regulate the claim on Skele-grow as a disease claim. The FDA defines 'disease' as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition."⁵⁴ The claim on Skele-grow would clearly be a damage clause claim. The broken bone is damage to the body such that the body does not function properly. A broken bone is a disease according to the FDA's definition in this particular area of regulation. This is contrary to the ordinary concepts of disease, injury, and broken bones. However, this is just as it should be for the purpose of

Proactive Approach to Dietary Supplement Regulation is Needed to Effectively Protect Consumers, 2010 U. ILL. L. REV. 1045 (arguing that DSHEA fails to protect consumers because of its reactive approach to dietary supplement regulation); see also *supra* text accompanying note 2.

53. Also, as will be shown, this shapes the FDA's regulations to some extent, and explains why products, such as those making anti-aging claims, are not heavily regulated (or the regulations are not enforced), while other products are regulated.

54. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 FED. REG. 1009 (proposed Jan. 06, 2000).

regulating Skele-grow.⁵⁵

Not all examples of overbreadth will be so unproblematic. Take pregnancy or aging, for example. These would clearly meet the state of health or causal clause of the definition of disease because they are states of health leading to biological dysfunction. The phrase “leading to” can only plausibly invoke a threshold causal concept. Pregnancy and aging cause dysfunction to a greater degree and with a greater probability than many conditions one ordinarily thinks of as disease. The FDA has dealt with these two problematic cases with pure stipulation: pregnancy and aging are not diseases.⁵⁶ However, given that the FDA must, on grounds of public policy, regulate any product that bears a claim “ingesting this product prevents pregnancy,” the FDA simply made a rule that explicitly forbade a dietary supplement from bearing “claims related to pregnancy on their products based on the agency’s recently issued structure/function rule.”⁵⁷

The FDA, in its so-called natural state exception, has also stipulated that certain conditions associated with certain “natural states” are not diseases. Again, we turn to pregnancy and aging. Conditions associated to these natural states are morning sickness and presbyopia, an inability to change eye focus from near to far and vice versa associated with aging.⁵⁸ Because such conditions fall into the natural state exception, they are not diseases. Of course, the natural state exception is misnamed—it provides an exception to the definition of disease for conditions associated with natural states, but not the natural states themselves (which as it turns out for the two examples provided above, pregnancy and aging, are also exceptions).⁵⁹

Underbreadth creates similar problems in relation to the ordinary conception of disease. Recall that there are two clauses to the FDA’s definition of disease: the damage clause and the state of health, or causal,

55. As it turns out, there are several other examples of overbreadth in which the FDA would get the definition wrong, but the regulation just right. For example, if a person is poisoned, she does not thereby have a disease, at least with some kinds of poison. Yet purported antidotes to poison must be regulated as are purported cures for diseases, and FDA has the power to so regulate by its definition of ‘disease.’

56. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, *supra* note 54, at 1020.

57. HUTT, *supra* note 25, at 281.

58. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, *supra* note 54.

59. This misnaming has created some confusion. For example, Hutt says: “FDA concluded that it is not appropriate to treat common nonserious conditions associated with natural states as diseases. These *conditions* include adolescence, the menstrual cycle, pregnancy, menopause and aging.” HUTT, *supra* note 25, at 281 (emphasis added). Surely, Hutt means to assert: “These natural states include adolescence, pregnancy and aging; and these conditions, respectively are growth, morning sickness and menopause.”

clause. On the one hand, the damage clause applies very well to injuries. Injuries such as broken bones, knife wounds, bullet wounds, and organ failure caused by trauma to the body are all instances of damage to a part of the body such that it does not function properly. On the other hand, the damage clause does not fully capture conditions that fall into the ordinary concept of disease. It is difficult to characterize the early stages of cancer as damage. Although it is true that cancer is a genetic mutation, a genetic mutation is not obviously damage to an organ, part, structure or function of the body such that it does not function properly (of course cancer might cause such damage, but that is another clause of the definition). The result is that a lot of regulatory weight is pushed onto the state of health clause of the FDA's definition.

The state of health clause captures many diseases, but not all. Presumably, the FDA would suggest that its state of health clause is truly counterfactual in the sense that the clause really means "state of health that *if untreated* leads (with a certain probability) to such dysfunction (of a certain degree)." The FDA can only plausibly mean the counterfactual variation since some diseases very rarely lead to dysfunction due to effectiveness of treatment, mitigation and prevention. So, it may seem at first that the FDA could easily deal with any underbreadth issue stemming from easily treatable diseases. However, there are diseases that simply develop so slowly that threats from overdiagnosis and overtreatment lead to greater dysfunction than does non-treatment. Some think that certain kinds of prostate cancer have this feature—that for reasons of overdiagnosis and overtreatment, the health outcomes are worse for those who get screened and then treated for prostate cancer than those who do not.⁶⁰ Clearly prostate cancer is a disease according to the ordinary conception, but certain kinds might not pass the threshold for "leading" to dysfunction.

The overbreadth and underbreadth analysis is very revealing. First, it shows that the FDA is shaping its regulation of disease claims in part by understandable political motives, such as the desire to avoid treating pregnancy as a disease. Second, it shows even though the FDA's definition is overbroad, this overbreadth leads to proper regulation, such as regulation of certain injury claims. Third, it shows that the FDA's definition of disease is problematic to apply even to ordinary disease, and that this likely results in regulatory problems for claims borne on any ingested products, especially dietary supplements.

60. See Michael Barry, *Screening for Prostate Cancer—The Controversy that Refuses to Die*, 360 N. ENGL. J. MED. 1351, 1353 (2009) (discussing two different large-scale studies and concluding that "[s]ome well-informed clinicians and patients will still see these trade-offs [of screening and treating versus non-screening] as favorable; others will see them as unfavorable").

It appears that FDA is defining ‘disease’ not by its public, stated definition in the statute, but by private rule. This rule is private because its criteria are known only to the FDA. There must be a reason that such biological conditions as pregnancy and aging are simply stipulated as non-diseases and yet some cancers are treated by the FDA as diseases even though they fail to meet the stated definition. The reason is their private definition of ‘disease.’ All things considered, it would be better to have a definition of disease that has no exceptions to it by regulation and is publicly known.

Now, turn to another sort of problem with the FDA’s definition of disease and the regulation of dietary supplements: The border between structure-function claims and disease claims is unclear. In particular, there is a grey area with respect to maintenance and prevention of illness, which dietary supplement labels exploit. Recall that structure-function claims may contain an assertion that a product may stimulate, maintain, support, regulate or promote structure or function.⁶¹ Now, one way of understanding health is just as proper function of the human organism. Therefore, a structure-function claim may contain an assertion that a product may stimulate, maintain, support, regulate or promote health. Moreover, it is plausible to think that health is the absence of disease in the human organism. Now, a structure-function claim may contain an assertion that a product maintains, supports, regulates, or promotes the absence of disease. Now the structure-function claim is starting to resemble a disease claim. The basic problem arises because if one adds to the definition of a structure-function claim the very intuitive propositions that (1) health is proper functioning and (2) health is the absence of disease in the human organism, what results is a disease claim, explicitly the type of claim dietary supplements are forbidden to make. So, dietary supplements cannot name diseases or make other claims too closely tied to the names or symptoms of diseases. And this is precisely the grey area of regulation that dietary supplement manufacturers exploit. It should be clear at this stage that the regulations are very difficult to enforce.

III. FDA’S PROPOSED DEFINITION OF ‘DISEASE’

Given the discussion above, whatever rule the FDA is following in delineating its class of disease claims, it is neither the ordinary concept of disease (since it covers injury claims, etc.), nor is it its own definition of disease (since it stipulates exceptions and suffers from underbreadth). In

61. FDA COMMISSION ON DIETARY SUPPLEMENT LABELS, *supra* note 46.

response to some of the problems mentioned above (especially the criticism that the damage clause does not capture diseases in an ordinary sense), and in an attempt to be more responsive to its goals, such as protecting health, the FDA sought to change its definition of disease through notice and comment rule-making. As a primary reason for changing its definition:

FDA tentatively concluded that it did not want to retain the older health claims definition because its use of the term 'damage' could be interpreted to limit the definition to serious or long-term diseases, and could imply that there needed to be pathological evidence of damage, which is not always present. For example, most mental illnesses have no evidence of anatomic damage, yet are clearly diseases.⁶²

The FDA proposed a new definition of disease by notice in April of 1998.⁶³ According to this proposed definition:

Disease or health-related condition means any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to this section or section 101.70).⁶⁴

Call the term defined the definiendum. Call the definition of the term the definiens. The definiendum is, in the proposed definition, not merely 'disease' but also "health-related condition." The reason for the inclusion of the term "health-related condition" is that its inclusion makes the account consistent with other parts of FDA regulation. A health-related condition is "a state of health leading to disease."⁶⁵ The most important change between the old definiens and the new is that the new one excludes the concept of damage from the definition. Also, in the first prong of the definiens, the dysfunction prong, the FDA asserts that in order for a

62. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, *supra* note 41.

63. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23625 (proposed Apr. 29, 1998).

64. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, *supra* note 41, at 23631, 23632.

65. *Id.*

dysfunction to constitute a disease, it must also have a manifestation of a characteristic set of signs or symptoms. In other respects, this new definition is similar to the DSHEA definition.

This proposed definition improves on the FDA's definition in several ways. First, it removes the concept of damage and allows for injuries to be understood purely in functional terms, such that an injury is a state of health causing dysfunction. Damage, therefore, is not essential to a regulatory definition.⁶⁶ Second, the proposed definition expands the definiendum to include more than 'disease.' The inclusion of "health-related condition" moves in the right direction, but the definiens of "health-related condition" is not wholly satisfactory. "Health-related condition" is defined as a state of health leading to disease (see above), which makes it seem that 'disease' is defined by the first definiendum while "health-related condition" is defined by the second definiendum. This is purely a pragmatic criticism, however, and does not necessarily undermine the definition conceptually. Moreover, some might find that treating an injury as just a state of health leading to disease to be counter-intuitive. Nevertheless, the revised definition is clearer than the DSHEA definition.

A purpose of the proposed definition is clear: to eliminate the concept of damage from the FDA's definition of 'disease,' in order to enhance regulation of drugs and dietary supplements by focusing on claims involving characteristic signs or symptoms. The FDA stated:

[T]he agency relied upon standard medical and legal definitions of disease as a basis for a proposed regulatory definition. The agency then used the proposed definition of disease to generate workable criteria, by applying the proposed definition to a wide variety of statements currently made by dietary supplement manufacturers to determine whether the statements claimed an effect on [sic] "disease," as tentatively defined. Based upon the information derived from these reviews, the agency developed the general criteria below.⁶⁷

Disease claims under the regulatory scheme are, in a manner of speaking, special kinds of structure-function claims. Under the old regime, dietary supplement structure-function claims are not drug claims, in part because the structures and functions they purport to regulate or maintain are neither associated with dysfunction paired with damage, nor lead to such dysfunction.

66. For example, a broken arm is a damaged arm, but it is also a dysfunctional arm. If, plausibly, where there is damage, there is dysfunction, and the new definition will omit nothing that the old definition included.

67. Regulations on Statements Made for Dietary Supplements, 63 Fed. Reg. 23,624, 23,625 (Apr. 29, 1998).

The FDA was concerned about standard disease claims and implied disease claims. Moreover, the Agency followed comments from a commission, members of which “were troubled about the wording of structure/function statements suggest[ing] that the most problematic wording is seen in statements ostensibly relating to ‘normal healthy function’ [sic] that actually imply the need to remedy an underlying abnormal or unhealthy state.”⁶⁸ This is a more recent concern and does not easily fit into the five values behind dietary supplement regulation discussed above. The concern is that the dietary supplement manufacturers would create a desire for their product that is both wasteful and potentially harmful. For example, the advertisement for Lucidrol might imply that lack of “tunnel vision” needs a remedy, and that with this remedy in place, a person “will achieve desired results—whatever they may be.” Another concern of FDA was that “[a] statement may contain an express or implied disease claim if it suggests that the product cures, mitigates, treats or prevents a disease or diseases by augmenting the body’s own disease-fighting capabilities.”⁶⁹ This is the foremost healthcare concern surrounding claims made by dietary supplements.

These illustrations of the FDA’s concerns more practically locate the problem. The FDA was preoccupied with its ability to regulate products bearing claims about treatment of migraine headaches and depression,⁷⁰ which in many cases are not accompanied by damage nor necessarily cause damage in any ordinary sense. Along this line, the FDA felt that it could regulate the claim “treatment of epilepsy” under its then-current regime, since epilepsy is a disease under the old definition, but the Agency was concerned that it could not regulate the claim “prevention of seizures” under its then-current regime.⁷¹

The FDA received criticism that aging, menopause, and other biological states/functions would be diseases under the proposed definition.⁷² The FDA denies this claim.⁷³ Whether pregnancy meets the proposed definition of disease is more controversial than whether pregnancy meets the current definition of ‘disease.’⁷⁴ Nevertheless,

68. *Id.* at 23,626.

69. *Id.* at 23,627.

70. *Id.*

71. Regulations on Statements Made for Dietary Supplements, 64 Fed. Reg. 36,824, 36,825 (July 8, 1999).

72. Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. 1,000, 1,019 (Jan. 6, 2000).

73. *Id.*

74. *See id.* at 1,020 (“FDA has reconsidered proposed § 101.93(g)(2)(iii), and has concluded that it is not appropriate, under DSHEA, to treat certain common, nonserious conditions associated with natural states as diseases. There are a wide variety of conditions

pregnancy plainly leads to dysfunction as much as many conditions classified as diseases in an ordinary sense.⁷⁵ The FDA was also concerned with the distinction between “lowers cholesterol” and “maintains healthy cholesterol levels.”⁷⁶ This exemplifies the grey area between disease claims and structure-function claims as discussed above. Ultimately, the FDA declined to revise its definition of ‘disease.’ According to the agency, “[t]he final rule classifies many more claims as structure/function claims than the proposed rule would have.”⁷⁷

Admittedly, the proposed definition is far from perfect. It would still leave the classification of pregnancy unresolved except by declaration of an exception, which is regulation by private definition (private, that is, to the FDA). Addressing the universal process of aging remains an issue. It certainly does not help by way of clarification that ‘disease’ shows up in the explanation of ‘characteristic set’ as part of the definition of ‘disease.’ Perhaps in this regard, the proposed definition of disease mimics the way the FDA’s definition of food makes reference to food as it is colloquially understood.

Two resources help to explain the FDA’s reasoning for its decision to retain its old definition: a National Law Journal article that details a meeting organized by the FDA to compare and contrast the two definitions of ‘disease’ and the Federal Register comments that explain why the FDA rejected their proposed definition and retained their old definition in the final rule. Both sources discuss the FDA’s reliance on the difficulty in conforming the proposed definition of disease to the concept of disease in a commonsense way. This reliance is surprising. A great deal of philosophical work has been done in explicating the concept of disease, and the FDA seems not to have explored these careful developments. Also, the FDA, for whatever reason, was very concerned with making the definition of disease correspond to the concept of disease, when it does not make this

representing impaired function of an organ or system that are associated with particular stages of life or normal physiologic processes. These stages and processes include adolescence, the menstrual cycle, pregnancy, menopause, and aging. FDA notes that, contrary to the comments, the proposed rule would not have classified these stages or processes themselves as diseases; it classified only certain abnormal conditions associated with these stages or processes as diseases. The conditions associated with these stages or processes can vary from common, relatively mild abnormalities, for which medical attention is not required, to serious conditions that can cause significant or permanent harm if not effectively treated.”).

75. See Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. 1,000 (Jan. 6, 2000) (highlighting FDA’s revised criteria as they apply to natural conditions such as menopause or pregnancy).

76. *Id.* at 1,018.

77. *Id.* at 1,004.

correspondence a priority in other areas for regulatory purposes (e.g. 'food' includes gum).

The FDA received over 235,000 comments during the notice/comment procedure.⁷⁸ Most of these were form letters, but over 22,000 were individual letters from the dietary supplement industry, trade associations, health professional groups, and consumers.⁷⁹ Not all of them had to do with the concept of disease.⁸⁰ Nearly all of the letters from the dietary supplements industry were *against* the proposed definition of 'disease.'⁸¹ Nearly all of the letters from health care providers, such as doctors, nurses, and organizations devoted to aspects of one or a set of diseases were *in favor of* the proposed definition, in part because the proposed definition corresponds better to the concept of disease and medical definitions of disease.⁸² The FDA set up a meeting between members of the health care community and regulatory experts in this area, and, while they could not settle on a definition of 'disease,' the conclusion was that because of the support of the healthcare community, the FDA would likely adopt the proposed definition in the final rule.⁸³ The final rule likely came as a great surprise to the panelists.

The argument in favor of the proposed definition was based on the overly restrictive damage element of the definition of 'disease.'⁸⁴ In particular, health professionals pointed out a number of recognized disease conditions for which it is not currently possible to identify physical damage to an organ, part, or system of the body, including most psychiatric diseases (depression, bipolar disorder, schizophrenia, and obsessive compulsive disorder, among others), and the early stages of certain metabolic diseases, including diabetes, genetic diseases, and nutritional deficiency diseases.⁸⁵

The FDA rejected this line of thinking because they suggested that 'damage' would be present in the following conditions:

The requirement of "damage to an organ, part, structure, or system of the body such that it does not function properly" indicates that a condition may be considered a disease if there is direct evidence of structural damage to an organ, part, structure, or system of the body, or indirect evidence of damage, indicated

78. Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. 1,000, 1,000 (Jan. 6, 2000).

79. *Id.*

80. *Id.*

81. *Id.* at 1,017.

82. *Id.*

83. Richard Wood et al., *Panel Debates New Dietary Supplement Regulations*, NAT'L L.J., Nov. 29, 1999, at B12.

84. Regulations on Statements Made for Dietary Supplements 65 Fed. Reg. at 1,017.

85. *Id.* at 1010.

by the failure of the organ, part, structure, or system of the body to function properly. This interpretation is appropriate because otherwise well-recognized psychiatric diseases, migraine headaches, hypertension, blood lipid disorders, and many other well-accepted diseases, could be excluded from coverage due to the lack of direct evidence of physical damage.⁸⁶

The quotation is included in full to demonstrate the FDA's problematic reasoning. First, the argument begs the question.⁸⁷ This is clearest in the second sentence, which that a counterexample to the statutory definition of disease somehow proves that the definition cannot imply the counterexample. Thus, the second sentence of the argument must be completely disregarded and, in fact, counts against the old definition (except the hypertension example). The first sentence is similarly problematic. The issue the FDA is trying to resolve is not the evidence of a disease or whether something may be considered a disease, but the criterion for disease. The evidence or reason for consideration is not the criterion. So, one easily can see why the old definition is rational on these lines of argument.

However, the FDA offers a stronger argument for retaining the old definition. The FDA stated that it believed that Congress, in the passing of the NLEA, "should be presumed to have been aware of the 1993 FDA definition of 'disease or health-related condition' and to have intended the FDA to use that definition."⁸⁸ Moreover, as the FDA notes, the background to the definition is Congress' intent to widen the scope of available structure/function claims for dietary supplements.⁸⁹ Narrowing the definition in order to restrict the scope would be contrary to congressional intent. Thus, the FDA does have good reason for retaining the old definition. Nevertheless, the arguments above suggest that Congress should adopt the proposed definition, even if the FDA cannot. Moreover, there is another way to view congressional intent such that adopting the new definition is consistent.

First, a strong majority of members of the health care industry was in favor of the proposed definition. The FDA and health care providers are primarily concerned that people will take supplements and forego better,

86. *Id.*

87. Begging the question here is to be understood in a technical way as identifying a kind of fallacy of reasoning, and not in the contemporary corruption of the phrase meaning, roughly, an answer to a question that evokes a further question. To beg the question in the technical way is to assume the truth of the conclusion in a reason for the conclusion.

88. Regulations on Statements Made for Dietary Supplements, 64 Fed. Reg. 36,824, 36,825 (July 8, 1999).

89. Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. at 1,017.

empirically grounded health care measures and that such unregulated products are dangerous to consumers. Health care practitioners have only a very modest interest, if any at all, in adopting the proposed definition, while the dietary supplement industry has a financial incentive to retain the old definition. While this consideration is not decisive, it does demonstrate what is at stake for the key parties involved in the regulations. Second, it is reasonable to assume that Congress intended the term 'disease claim' to cover, at the very least, conditions that fall under the ordinary concept of disease and not capture other conditions that are not thought to be diseases. Yet, as has been shown, the old definition does not achieve this end. Since "damage" is not technically defined in the statute, and an ordinary definition of "damage" would lead to improper application, the FDA should use a commonsense approach. Third, the FDA currently asserts that it has the power to redefine 'disease.' The FDA, after it offered its own arguments for retaining its old definition of disease, said that "[i]f experience shows a public health need for a different or broader definition, however, the FDA will consider initiating a rulemaking to amend that definition."⁹⁰ Revising the definition is within the range of the FDA's claimed authority, so long as there is need for change.

Moving forward, the FDA has several options. It could retain its old, statutory definition, adopt its proposed definition, or adopt an alternative definition. The next section explains a philosophical definition of disease and explores its potential application in FDA regulation of dietary supplements.

IV. A NATURALIST PHILOSOPHICAL ACCOUNT OF DISEASE

Philosophers (and healthcare practitioners thinking philosophically) have given a great deal of thought to the concepts of health and disease. Although there is disagreement on the concept of disease, one branch of philosophers have argued for a definition of the term 'disease' that is similar to the FDA's proposed definition. An examination of a key philosopher's definition of disease will be helpful in analyzing the underlying conceptual issues of the debate between the FDA definitions of 'disease.'

Broadly speaking, there are two philosophical schools of thought on the concept of health and disease. The "evaluative" school members argue that a disease is a biological function or status coupled with a subjective

90. Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. at 1,010.

negative evaluation of that function or status.⁹¹ The “naturalist” school members argue that a disease is biological functioning outside, and below, the range of normal biological functioning. For this school, the concepts of health and disease are value-free in the sense that ‘health’ and ‘disease’ are not defined by essential reference to values. Rather, they are defined only in reference to biological functioning of certain sorts. Although the debate between the evaluative school and the naturalist school continues, this Comment focuses on the naturalist account of disease and one of its most prominent voices, Christopher Boorse.

In a series of papers culminating in his essay *A Rebuttal on Health*, Boorse develops and defends the naturalist position. Boorse calls his theory the “Biostatistical Theory of Health.” “Health,” according to Boorse, is defined by four concepts:

1. The *reference class* is a natural class of organisms of uniform functional design; specifically, an age group of a sex of a species.
2. A *normal function* of a part or process within members of the reference class is a statistically typical contribution by it to their individual survival and reproduction.
3. A *disease* is a type of internal state which is either an impairment of normal functional ability, i.e. a reduction of one or more functional abilities below typical efficiency, or a limitation on functional ability caused by environmental agents.
4. *Health* is the absence of disease.⁹²

First, Boorse identifies health as normal function of a part or process that statistically contributes to individual survival and reproduction. Second, Boorse separates individuals on the basis of sex, age and race; health is relative to the extent to which one’s biological functioning statistically meets the ends of individual survival and reproduction according to one’s sex, age and race. Disease is then defined as operation below the statistical normal range (for one’s sex, age and race) for two reasons: impairment or environmental agents. Conceptually, there is room for a class of “super-functioning” or positive health, which is part functioning above the normal range.⁹³

91. See TRISTRAM ENGELHARDT, JR., *The Concepts of Health and Disease, in* EVALUATION AND EXPLANATION IN THE BIOMEDICAL SCIENCES 125–43 (Tristram Engelhardt & Stuart Spicker eds., 1975) (arguing that the concept of health is essentially value-laden); see also MAHESH ANANTH, *IN DEFENSE OF AN EVOLUTIONARY CONCEPT OF HEALTH: NATURE, NORMS, AND HUMAN BIOLOGY*, 107–15 (2008) (laying out the debate between naturalists and the opponents of naturalism about the concept of health, and ultimately defending a hybrid conceptualization that is predominantly naturalistic).

92. CHRISTOPHER BOORSE, *A Rebuttal on Health, in* WHAT IS DISEASE? 7–8 (James M. Humber & Robert Almedert eds., 1997).

93. Boorse has a bell curve chart that illustrates an idealization of his definitions of “health” and “disease.” The majority of people fall into the middle sections, with the

Boorse's definitions of "disease" and "health" do not include the concept of damage (as in the FDA's existing definition) or the concept of characteristic symptoms or signs associated with diseases (as in the FDA's proposed definition). An "exchange" between the FDA and a critic of the FDA's proposed definition is illuminating:

Most of these comments [from the dietary supplement industry] argued that the new [proposed] definition is too broad, sweeping in many minor deviations or abnormalities that are not diseases. (Many of these comments did not appear to have understood that the definition required not only a deviation, but one that 'is manifested by a characteristic set of one or more signs or symptoms.')

⁹⁴ Given its comments, however, the FDA does not seem to understand this implication. It does not acknowledge "borderline" cases for the criteria of damage, sign and symptoms, and dysfunction.

Here is a helpful contrast between either of the FDA's definitions and Boorse's definition. The FDA's definitions each have at least two difficult grey areas: one for dysfunction and one for the associated physical property, whether it be damage or characteristic signs. With Boorse's definition of disease there is just the grey area with dysfunction. Moreover, without the concept of damage, Boorse's definition of disease easily captures leukemia and colon cancer in a way that FDA's definition can only get in an expanded, non-colloquial sense of "damage" and "dysfunction."

One might object to Boorse's definition on the grounds that there is no clear line between normal function and disease (at below normal) or super-function (at above normal). Admittedly, with Boorse's definition, there will be hard cases. An example that recurs throughout discussion on this

diseased having lesser function, and those with "positive health" on the higher functioning side of the bell curve. *Id.*, at 8.

94. 65 Fed. Reg. 1000, 1009. The FDA seems here to have been influenced by a medical doctor's suggestion from the FDA meeting on the proposed definition of disease during the notice/comment period. See Richard Wood et al., *Panel Debated New Dietary Supplement Regulations: Focus was on FDA's Definition of disease, 'Natural States' and 'Implied' Disease Claims*, 22(14) NAT'L L.J. 10 (Nov. 29, 1999) (discussing questions posed by the FDA).

topic, including this Comment, is that of blood pressure and hypertension. There is a range of normal blood pressure. The medical community sets the standard for when blood pressure becomes a disease (hypertension). There is a grey area perhaps, with pre-hypertension, a zone that doctors identify between normal blood pressure and hypertension. Yet the medical community establishes certain protocols for treatment at each stage. Those in the upper level of the normal range are not given drugs, but rather, lifestyle suggestions, and perhaps a dietary supplement, such as an Omega-3 Fatty Acid. If the blood pressure increases, then a drug-intervention is used. This is a model of how Boorse's account works through the grey areas. The categories of normal function are set by particularized statistical findings within one's age, sex, and perhaps race. The medical community sets the standards for proper treatment. Sometimes, the treatment standards are changed by the medical community (for example, if the category of hypertension were to be changed slightly to include lower blood pressure ranges), but the decision-making is performed by those best situated to make decisions. There is no better way forward when applying the concept in the real world. Thus, while there are grey areas of function, Boorse's theory fares much better than either of FDA's approaches.

Other benefits would stem from incorporating Boorse's definitions of health and disease into the regulatory framework of dietary supplements and drugs. First, as explored above, the concept of pregnancy caused problems for both of the FDA's definitions of disease. The FDA maintained that pregnancy, under either of their definitions, was not a disease, yet pregnancy meets the conditions of the definitions, and products that claim to prevent and "cure" pregnancy must be regulated as drug claims. Using Boorse's model prevents such awkwardness: since pregnancy serves an end to human functioning, it is not a disease. It does sometimes conflict with another one of Boorse's proposed ends, that of individual survival, but the overall framework allows room for the claim that pregnancy is not a disease. The FDA's current definition of "drug" still captures any product that bears a claim that it prevents pregnancy, but it is unclear on what grounds the FDA imposes that regulation.

In this area, there is an untoward implication of Boorse's definition—that a woman taking birth control pills is thereby giving herself a disease. Although unsatisfactory for political reasons, it seems conceptually within the bounds of disease, and plausibly, infertility in the absence of birth control in a young woman is a disease.⁹⁵ Moreover, Boorse's account deals

95. Since Boorse's definition is relative to one's age, the infertility in a young woman is a disease, yet infertility in an older woman is not a disease. Infertility treatment in an older woman would then be an elective health care treatment, not a disease cure. This is

better with “natural states” and conditions associated with such states. The menstrual cycle, for example, is one such state. Because it has a reproductive function and is statistically normal relative to certain ages, normal menstrual cycle function is not a disease in Boorse’s account of health and disease in a straightforward way. Moreover, the natural state of aging, and conditions associated with aging, is easily accounted for by Boorse’s definition, which considers age when determining normal function.

Boorse’s definitions of health and disease highlight a problem with the FDA’s proposed definition of disease. The proposed definition does not state clearly that functioning outside the range of normal must be a deficiency of function.⁹⁶ The terms that the proposed definition uses are “deviation from,” “impairment of,” or “interruption of” the normal structure or function of a part or whole of the organism. The terms “deviation from” and “interruption of” do not necessarily indicate a dysfunction. For example, Usain Bolt has a level of functioning in his sprint running that is an extreme deviation from what is normal, yet he does not thereby suffer from a disease. There are many such examples of people functioning outside, but above, the range of normal.

The FDA is then reduced to defining the dysfunction of disease in terms of impairment of function. The concept of impairment works well for some functions of diseased states, but not all. “Impair” is defined as “to damage or make worse or as if by diminishing in some material respect.”⁹⁷ The standard dictionary definition of impair does not get at the nerve of the disease concept, at least in many cases, since impairment refers to some factor that causes some further damage or dysfunction or diminished health. While some diseases behave this way, others do not; they are in themselves dysfunctions. For example, if stress causes hypertension, the disease is hypertension, not stress. In effect, the lack of a clear “below normal” functioning requirement in the definition of disease reduces the first disjunct of the definition (dysfunction) to the second (state of health causing later dysfunction), or at least implies this in some cases. Boorse’s definition of disease uses the concept of impairment and limitation caused by environmental agents. However, Boorse has a way around the around the objection expressed above by reference to a technical distinction

intuitive, since pregnancy past a certain age is contrary to the individual survival of the would-be mother.

96. This is one way in which the current definition is superior to the proposed definition.

97. MERRIAM WEBSTER’S COLLEGIATE DICTIONARY 581 (10th ed. 1998). The fonts and stylistic markings are exactly as they appear in the dictionary.

between internal and external states.⁹⁸ Boorse builds the concept of “internal state” into his definition of disease. Yet, the FDA does not have recourse to such a distinction in the proposed definition. The FDA’s definitions can be improved by eliminating or supplementing the “impairment condition” of the definition in order to capture the notion of functioning below normal so as to constitute dysfunction, and not just outside normal functioning.

Boorse admits that his definition of disease captures what one ordinarily thinks of as injuries.⁹⁹ Boorse’s definition has precisely the “good overbreadth” that the FDA’s definitions do for regulatory purposes. Boorse likely would think that further refinement of the definitions of “health” and “disease” would rule out such overbreadth, yet, for the purposes of regulation, such overbreadth is essential.

In summation, Boorse’s definition of disease is conceptually superior to either of the FDA’s definitions, and leads to clearer application.¹⁰⁰ With regard to the FDA’s current definition, a central problem is the inclusion of the concept of damage. Neither health care practitioners, nor philosophers, nor ordinary people think that disease is necessarily accompanied by damage or a health state leading to such dysfunction. Another central problem is that pregnancy meets the old definition of disease, a statement that the FDA wishes to avoid. Boorse’s theory dodges these two objections, first by not using the concept of damage, but of deviation from, and below, the normal range of function; and, second, by including reproduction as an end state for normal functioning. On Boorse’s account, the FDA could regulate any product that claims to prevent pregnancy because it meets the definition of a drug as a product intended to alter the structure and function of the body, and such a claim does not meet the conditions of a disease claim.

Boorse’s theory also fares better than FDA’s proposed definition. As noted above, the requirement that a disease have characteristic signs or symptoms is either vacuous, since dysfunction will necessarily always have a sign or symptom, or it is circular, since it uses “disease” in order to define “disease.” Alternatively, if the internal “disease” term is not meant in a technical way, then this would exclude injuries (and poisonings, etc.) from inclusion in the set denoted by the technical definition, which the FDA

98. BOORSE, *supra* note 92 at 67–69.

99. *Id.* at 6 (suggesting that “injuries, poisonings, environmental traumas, growth disorders, functional impairments, [and perhaps other unspecified conditions] inconsistent with perfect health” all fall within his definition of disease). It is unclear why Boorse thinks that growth disorders fall within the ordinary concept of disease.

100. The regulatory implications of this incorporation will be discussed in the next section of this Comment.

would ideally have jurisdiction over in order to regulate effectively. Second, the FDA seems to miss a key implication of the fact that normal function is a range, and not a precise point. Third, the proposed definition does not adequately account for sub-normal function, instead of above normal function, as one would be in a kind of super-functioning (impairment is not up to the task, at least in the straightforward way the FDA seems to think). Fourth, the proposed definition, at least by the FDA claim, classifies pregnancy as a non-disease, despite its meeting the conditions of the proposed definition of "disease." Boorse's definition of disease has none of these problems.

Moreover, Boorse's definition of disease would effectively distinguish some of the claims that have troubled the FDA. The FDA, which can regulate claims of treating epilepsy as a drug claim, was concerned that it would be powerless to regulate the claim that a product "prevents seizures." Boorse's definitions of "health" and "disease," could deal with this simply since seizures are below normal function to such an extent that that functioning constituted a disease. Moreover, migraine headaches, if persistent, would be below normal functioning of the brain or some other part of the body, and thus persistent migraine headaches would be classified as a disease. Depression is somewhat more complicated. The FDA, in adopting Boorse's definition, could treat depression as a biological dysfunction, and thus a straightforward disease. Alternatively, the FDA could treat depression as a mental dysfunction, and thus not a straightforward disease on Boorse's (or either of the FDA's definitions for that matter) account. Having said this, there is no reason to think that the general statistical model that Boorse develops cannot be also extended to drawing a line between normal mental function and mental dysfunction. The issue of "mental health" is quite difficult, and Boorse's account of health and disease does no worse than the FDA's definitions, and Boorse's biostatistical account of health can naturally extend to a mental-statistical account of mental wellness or health.¹⁰¹ Perhaps it is likely that depression is both a biological and psychological phenomenon, so a mix of statistical accounts would be appropriate for at least many kinds of depression.

V. TWO PROPOSALS FOR FUTURE FDA REGULATION

As noted above, the FDA, in its explanation for retaining its old definition of disease, said that "[i]f experience shows a public health need

101. Indeed, Boorse tentatively suggests such an extension. BOORSE, *supra* note 92 at 149–50.

for a different or broader definition, however, FDA will consider initiating a rulemaking to amend that definition.”¹⁰²

The FDA should adopt Boorse’s definition. The agency defines disease in this technical way only for 21 U.S.C. § 343(r)(6), the section that sets out the dietary supplement regime, and the gap between the technical definition and the colloquial definition has led to some implausible consequences. In adopting Boorse’s more conceptually plausible definition of disease for 21 U.S.C. § 343(r)(6), the FDA could close the gap.¹⁰³ Boorse’s definition can readily be integrated into FDA dietary supplement regulation. It defines disease in terms of structure and function; thus it suits the FDA definition of drug as a product intended to alter the structure or function of a person. Boorse’s definition is overbroad compared to the colloquial concept of disease, since it includes injuries and poisonings, but it is overbroad in a way that health care practitioners and the FDA itself seem to (and should) want.

A second reason follows from FDA’s assertion that it has the power to change its definition of disease for regulatory purposes if there is sufficient need. What all of the overbreadth and underbreadth criticisms show is not so much that there is a regulatory problem with drugs, but, rather, that since the FDA cannot easily include that which by all accounts it ought to regulate under the capture of disease, then it cannot possibly do the work it needs to for the vague claims of dietary supplements. Moreover, even if looking at intent rather than the exact text, a broad construal of congressional intent is to have a definition of disease that works best for regulatory purposes, and does not, for example, classify pregnancy as a disease, or somehow rule out what one commonly thinks of as disease as from a regulatory perspective disease, such as the examples above of slowly-developing diseases without colloquial damage or future, further dysfunction. Thus, there is good reason to believe that the FDA could adopt Boorse’s definition of disease without congressional action in accordance with the FDA’s own claims.

A more provocative proposal for the FDA regulation of dietary supplements is to eliminate reference to disease altogether in dietary

102. 65 Fed. Reg. 1000, 1010.

103. The exception for diseases from dietary insufficiencies, such as scurvy, should be included in Boorse’s definition for regulatory purposes. The FDA also uses the concept of “disease” in its basic definition of “device,” a primary, large regulatory jurisdiction of the FDA. The FDA might be able to adopt Boorse’s definition outright in the device jurisdiction, and probably should not include an exception for dietary insufficiency diseases, such as scurvy in that arena. This is outside the scope of this Comment, but there should be great attraction in having an almost completely unified definition of disease that stands throughout FDA’s various jurisdictions.

supplement and drug regulation. The FDA has trouble with using “disease” in its regulations. First, the FDA relies on the ordinary concept of disease in order to identify the relevant class of disease claims (e.g., colon cancer), since the concept of damage is not present in such cases, nor is future, other dysfunction statistically indicated in a range of such cases. Second, the FDA asserts, against its own definition, that some conditions that meet its definition of disease are not diseases on the definition (e.g., pregnancy and aging). Third, the FDA is rationally committed to claiming that certain conditions that are not diseases meet the disease definition (e.g., injuries, poisonings). Fourth, in order to deal with these cases in just the right way, the FDA can make use of part (C) of its definition of “drug” exclusively which allows for the FDA to assert jurisdiction over any product that is intended to alter structure or function. Fifth, the FDA regulation under 21 U.S.C. § 343(r)(6) is not doing as much conceptual regulatory work as had been thought with the definition of disease; nor is the ordinary concept of disease within the definition of drug doing regulatory work. Instead, the FDA relies on pure claims involving alterations to structure and function.¹⁰⁴

The FDA's proposed definition fares better with the first problem (and perhaps the second), but it creates new problems by resting the definition of disease on the concept of impairment, which is more suited to injuries than to disease. Furthermore, and somewhat superficially, the FDA does not capture the more plausible understanding of the concept of normal function as a range, rather than a precise point of normal functioning or structures. Boorse's definition of disease does away with these problems, and it deals with the two unhappy further implications of the proposed definition, yet it does not deal with the other problems.

The FDA could adopt Boorse's definition of disease, yet not regulate what falls under the definition *as disease*; rather, the criterion merely lays out what is to be regulated. Thus, the FDA would regulate all products that claim to alter a type of internal state, which is either an impairment of normal functional ability, i.e., a reduction of one or more functional abilities below typical efficiency, or a limitation on functional ability caused by environmental agents relative to age, sex and race and the ends

104. Another way of characterizing the argument is that the FDA can assert jurisdiction over products that meet either the “disease” part of its definition of “drug” or the “(other than food) intent to alter structure or function” part of its definition. Since there is tension between the two understandings of “disease” (the “drug” definition is not technical, but the 21 C.F.R. § 101.93 definition is technical), then the focus falls in some cases on the “(other than food) intent to alter structure or function” part. However, so this argument goes, there is no substantive “carve-out” for clear application—merely asserting that the definition does not apply to so-called “foods” does not provide a clear, substantive regulatory criterion.

as judged by individual survival and reproduction.¹⁰⁵ In order to capture claims such as those made by Lucidrol, the FDA would need to regulate claims that assert that a product can take one *above* the range of statistically normal functioning—into “super-functioning.”¹⁰⁶ In order to capture birth control pills, the FDA would need to assert jurisdiction over anything that claimed to put one below the range of normal functioning. The resulting rule is quite straightforward: Any claim that asserts a shift from one zone (of below, normal, or super-functioning) to another zone is a claim that must be regulated with drug claim scrutiny. A great confusion regarding FDA regulation is how two seemingly equivalent claims can be treated differently—a claim that a product helps maintain normal function is considered a structure-function claim, yet if the same product stated it could prevent later dysfunction, it would be considered a disease claim. The proposal just expressed makes sense of the two different claims—that dietary supplements cannot bear claims that assert or imply that taking the substance prevents one from dropping into lower part- or system-dysfunction (that is to say—that one would drop into the lower level of functioning without the product), it merely helps the system function within the normal range. Any claim that merely asserts maintenance within the normal zone of functioning is allowed as a kind of health claim (and there are subdivisions within this class of health claims classification along the lines of the health claims discussed above, with the exception of disease-prevention claims—a kind of health claim in the current regulatory regime—which would then fall either to a middle class of regulatory scrutiny, or drug-scrutiny, which they almost do already).¹⁰⁷ To illustrate the potential consequences of such a regime, Lucidrol’s claim would be brought under FDA drug-scrutiny (and therefore need pre-approval after testing, etc.), whereas Alpha Lipoic Acid’s claim might be allowed as one of the kinds of health claims, which seems appropriate given current scientific knowledge of antioxidants.

This second proposal, a change in the FDA regulatory system, might require congressional action. It is unclear whether the FDA’s power to change its definition of disease includes the power to stop calling what it

105. For regulatory purposes, the FDA should keep the nutrient deficiency exception even if it were to adopt Boorse’s definition in the way proposed.

106. The Federal Trade Commission and the National Advertising Division of the Council of Better Business Bureaus, Inc. provide additional oversight of dietary supplement claims, especially performance-enhancing dietary supplement claims. John E. Villafranco & Andrew B. Lustigman, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission, Food and Drug Administration and National Advertising Division*, 62 FOOD & DRUG L.J. 709 (2007).

107. Claims that assert maintenance within low level functioning and super-functioning zones would be rare, and would likely be regulated with drug claim scrutiny.

regulates “claims about health and disease,” opting instead, on the second proposal, for regulating claims about biological functions and effects on biological functions. Nevertheless, it would be a *vast* improvement over the existing system—a *significant* improvement over an adoption of the proposed definition of disease, and a *moderate* improvement over the adoption of Boorse’s definition of disease. What is clear is that the second proposal is true to the idea exemplified in the discussion throughout this Comment that the FDA is not only concerned with regulating claims about products that treat, cure, mitigate or prevent diseases as diseases are colloquially understood. Rather, the FDA is concerned with regulating claims about all sorts of conditions, such conditions unified by the concept of biological dysfunction.

This second proposal of dropping the phrase “disease” altogether from the identification of the set of the regulated claims borne by food and drugs is offered as a provocative proposal. Yet the core idea has appeal—neither drugs nor dietary supplements are limited to “bringing up” one’s function from disease or near-disease functioning. In addition to capturing the concepts of treatment or prevention of injuries, poisonings, commonsense diseases, etc., there is the concept of performance-enhancing (as Lucidrol’s label asserts). Boorse’s definition of health and the more radical proposal could each deal with these claims in their own unified way. Yet as it stands, the FDA’s current regulatory regime is the worst of the four possibilities under consideration.

CONCLUSION

What is clear is that adopting Boorse’s definition is within the claimed power of the FDA, given need for change. The values expressed above, such as foregone healthcare, public health, waste of money and others suggest that there is a need for change. Boorse’s definitions of health and disease would remedy some of the regulatory mess that the FDA has created with its old definition of disease. Moreover, the dietary supplement manufacturers would benefit to some extent by a clearer regulatory regime (especially since, as noted above, the FDA seems to be making exceptions to its definition by using what can only be described as a private principle or no principle at all). By not including a definitional element of damage (or causing damage-dysfunction), Boorse’s definition would more clearly map onto a commonsense way of regulating dietary supplements. As implied above, this proposal would not go so far as to capture the claim borne by Lucidrol, but, like the FDA’s claims about its proposed definition, it would give the FDA a better tool by which to regulate dietary

supplements. Examples such as claims about persistent migraine headaches and seizures might be the most practical examples of improved regulations with Boorse's definition in place, but the principled clarity and simplicity would also be of great benefit.